



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

urged
10/29/99 BNC
HFI-35 million

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

October 21, 1999

WARNING LETTER

NWE-05 -00W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James R. Fox, President/Owner
Dave Handrigan Seafoods
280 Great Island Road
P.O. Box 76
Narragansett, Rhode Island 02882

Dear Mr. Fox:

On September 10, 13, 14, and 16, 1999, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing plant, Seafresh USA, Inc., located 35 Walts Way, Narragansett, Rhode Island. The Investigator documented serious violations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123), and the Good Manufacturing Practices (GMPs) requirements in 21 CFR 110. These violations cause your tuna processed by your firm, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

As a Domestic Processor:

1. Monitoring record data is missing in the Receiving of Tuna CCP according to your HACCP plan, 21 CFR §123.6(c)(7), for example:

- (a.) of the nine (9) receiving records reviewed, the six (6) receiving records dated 9/5/99, 9/4/99, 8/24/99, 8/21/99, 8/19/99, and 8/17/99 did not contain one or more of the seven (7) elements the Tuna Handling Certificate, Harvest Vessel Record, or similar receiving record must document. The seven elements are:

[REDACTED]

Further corrective actions were not followed for these CL deviations as called for in your HACCP plan for tuna.

- (b.) of the nine (9) receiving records reviewed, the four (4) receiving records dated 9/5/99, 9/4/99, 8/24/99, 8/21/99, and an invoice dated 8/6/99 did not indicate if there was an adequate [REDACTED] or other [REDACTED] at the time of delivery.

2. Monitoring record is missing in the Raw Material Storage CCP according to your Tuna Handling HACCP plan, 21 CFR §123.6(c)(7), for example:

- (a) of nine (9) records reviewed, one (1) tuna received on August 19, 1999, had an internal temperature above [REDACTED] degrees. According to your HACCP plan [REDACTED] is added if necessary, until a [REDACTED] degree core temperature is reached within [REDACTED] of death. The internal temperature of the tuna was taken the next day but with no time indicated; further, the core temperature of the fish was still above [REDACTED] and no further temperatures, nor corrective actions were taken.

3. Monitoring records are missing at The Holding (Finished Product Storage) CCP according to your Tuna Handling HACCP plan, 21 CFR §123.6(c)(7), for example:

- (a.) of nine (9) receiving records reviewed, the four (4) receiving records received on 9/5/99, 9/4/99, 8/24/99, 8/21/99, did not show if [REDACTED] was performed according to your HACCP plan.

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your seafood processing plant. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these violations and all violations at your firm. Failure to achieve corrective action may result in further regulatory action without further notice. These actions may include seizure or injunction under the Federal Food, Drug and Cosmetic Act. In addition, failure to correct the above deficiencies may affect your firm's ability to obtain European Union certificates. As you know, FDA, as a service to

Seafresh USA, Inc.
P. O. Box 786
35 Walts Way
Narragansett, RI 02882
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the US seafood industry to facilitate the free flow of trade, has voluntarily undertaken to certify that seafood exports meet the EU's food safety requirements. Unless the deficiencies are corrected, FDA may remove your firm from the EU list. In addition, until these deficiencies are corrected, the agency may not issue EU certificates for shipment.

During the inspection our Investigator determined that you imported tuna from Greece and that [REDACTED] certified that the tuna was processed in accordance with the HACCP regulations. In order for your affirmative step to be complete and in compliance you must also maintain on file a copy in English of their HACCP plan (21 CFR §123.12(a)(2)(ii)(D)) or you may perform any of the other affirmative steps included in 21 CFR §123.12(a)(2)(ii).

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation demonstrating that corrections have been made. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Bruce R. Ota, Compliance Officer, at the noted above. If you have any questions concerning this matter, please contact Mr. Ota at (781) 279-1675, x119.

Sincerely,

/s/

John R. Marzilli
District Director
New England District Office